

From the INTERNATIONAL BUREAU

PCT

**NOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

(PCT Rule 72.2)

To:

KYOWA HAKKO KOGYO CO., LTD.
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JAPON

RECEIVED

MAY. 02. 2005.

I.P. DEPT

Date of mailing (day/month/year) 21 April 2005 (21.04.2005)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference 1496	
International application No. PCT/JP2003/008478	International filing date (day/month/year) 03 July 2003 (03.07.2003)
Applicant KYOWA HAKKO KOGYO CO., LTD. et al	

1. Transmittal of the translation to the applicant.

The International Bureau transmits herewith a copy of the English translation made by the International Bureau of the international preliminary examination report established by the International Preliminary Examining Authority.

2. Transmittal of the copy of the translation to the elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following elected Offices requiring such translation:

AZ, CA, CH, CN, CO, EP, GH, KG, KR, MK, MZ, RO, RU, TM

The following elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, BA, BB, BG, BR, BY, BZ, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, ES, FI, GB, GD, GE, GM, HR, HU, ID, IL, IN, IS, JP, KE, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MN, MW, MX, NI, NO, NZ, OA, OM, PG, PH, PL, PT, SC, SD, SE, SG, SK, SL, SY, TJ, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report.

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Masashi Honda
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Translation

PATENT COOPERATION TREATY

PCT/JP2003/008478



PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 1496	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/JP2003/008478	International filing date (day/month/year) 03 July 2003 (03.07.2003)	Priority date (day/month/year) 03 July 2002 (03.07.2002)
International Patent Classification (IPC) or national classification and IPC C07D 317/72, A61K 31/357, A61P 1/04, 3/10, 9/02, 9/04, 9/10, 11/02, 11/06, 13/12, 17/02, 17/06, 25/24, 25/28, 29/00, 31/18, 37/02, 37/08, 43/00, C07C 51/377, 65/21, 65/03		
Applicant KYOWA HAKKO KOGYO CO., LTD.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 25 December 2003 (25.12.2003)	Date of completion of this report 02 July 2004 (02.07.2004)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

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I. Basis of the report

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed
- ☐ the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the claims:
pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the drawings:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
☐ paid additional fees.
☐ paid additional fees under protest.
☒ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
☒ not complied with for the following reasons:

See supplemental sheet

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☐ all parts.
☒ the parts relating to claims Nos. 1-8

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of IV. 3.

The claims set forth the following two groups of inventions.

(1) The inventions set forth in claims 1-8, of a process for producing compounds represented by formula (VII) from a compound represented by formula (V).

(2) The inventions set forth in claims 9-11, of a process for producing compounds represented by formula (II) from a compound represented by formula (I).

The inventions in (1) and the inventions in (2) above do not have a common technical feature, and cannot be said to constitute a group of inventions so linked as to form a single general inventive concept.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1, 6-8	YES
	Claims	2-5	NO
Inventive step (IS)	Claims	1, 6-8	YES
	Claims	2-5	NO
Industrial applicability (IA)	Claims	1-8	YES
	Claims		NO

2. Citations and explanations

The following document is cited in the international search report.

Document 1: EP 0771794 A1

Document 1 discloses a process for producing 1,3-benzodioxole-4-(aromatic substituted)methyl-2-spiro-cycloalkanes by reacting a (1,3-benzodioxole-2-spiro-cycloalkane)-4-carboxylic acid ester with a methyl-substituted aromatic compound. Therefore, the novelty and inventive step of the production processes claimed in claims 2-5, as stipulated in PCT Article 33(2) and (3), are taken away by the disclosure in document 1.

However, document 1 does not disclose a production process claimed in claims 1 and 6-8, which is a process for producing 1,3-benzodioxole-2-spirocycloalkane derivatives which includes a step wherein a 2,3-dihydroxybenzoic acid derivative is reacted with a cycloalkene derivative. Moreover, by adopting an aforementioned step, the process for producing 1,3-benzodioxole-2-spiro-cycloalkane derivatives as set forth in claims 1 and 6-8 offers the marked advantageous effect that isolation and purification of the intermediates is easy, since it does

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not involve intermediates which are oils and are difficult to handle, and this advantage is not obvious to a person skilled in the art, even when general knowledge of the art is considered. Therefore, process for producing 1,3-benzodioxole-2-spirocycloalkane derivatives as set forth in claims 1 and 6-8 is novel and involves an inventive step as stipulated in PCT Article 33(2) and (3).